UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION
NO. _____

CARY MASSA,

v.

GENENTECH, INC. and XOMA (US) LLC,

COMPLAINT FOR DAMAGES

1. Strict Liability-Failure to Warn
2. Strict Products Liability
3. Negligence
4. Breach of Implied Warranty
5. Breach of Express Warranty
6. Fraud by Concealment
7. Gross Negligence

DEMAND FOR JURY TRIAL

JURSIDICTION AND VENUE

1. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(a)(1). The amount in controversy is well over $75,000.00 and diversity of citizenship exists because Plaintiff is a citizen of Texas and Defendants are citizens of Delaware and California.

2. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a). A substantial portion of the events and omissions giving rise to this lawsuit occurred in this District, and the Court has personal jurisdiction over each of the parties as alleged throughout this Complaint

PARTIES

3. Plaintiff Cary Massa is a citizen of the United States and the State of Texas, currently residing in Fort Bend County, Texas

4. Defendant GENENTECH, INC. ("GENENTECH") is a Delaware corporation with its principal place of business at 1 DNA Way; South San Francisco, California 94080.

5. Defendant XOMA (US) LLC ("XOMA") is a Delaware corporation with its principal place of business in Berkeley, California, and is a wholly owned subsidiary of XOMA, LTD., a

business entity formed under the laws of Bermuda with its principal place of business in Berkeley, California.

COMMON FACTUAL ALLEGATIONS

A. MEDICAL/SCIENTIFIC BACKGROUND CONCERNING RAPTIVA AND SERIOUS HEALTH RISKS

6. Psoriasis is a chronic, non-contagious autoimmune disease which affects the skin. The disease is not life threatening and does not induce irreversible injury to the skin or other organs. Plaque psoriasis, the most common form of the disease, is characterized by inflamed patches of skin ("lesions") topped with silvery white scales. According to the National Institutes of Health, as many as 7.5 million Americans have psoriasis; approximately 2.3 million Americans have the more severe plaque psoriasis. While there are a number of medications that may help control the symptoms of psoriasis, there is currently no cure.

7. Conventional psoriasis treatment consists of topical agents ($1,000 annual cost per person), ultraviolet therapy, ($3,500 annual cost), cyclosporin ($3,000 annual cost), and methotrexate ($800 annual cost).

8. In the past decade, there have been considerable advances in the understanding of pathogenesis of psoriasis. It is now recognized that the aberrant activation and migration of T-cells into the skin is central to the disease. A T-cell is a type of white blood cell and the cell the body uses to fight infection.

9. At issue in this case is the psoriasis prescription drug RAPTIVA. RAPTIVA belongs to an entirely new class of drugs known as biologics.[1] The term "biologics" is used to describe medications that are produced by means of biological processes involving recombinant DNA technology. These medications are usually classified into one of three types: (1) substances that are (nearly) identical to the body's own key signaling proteins such as a growth-stimulating hormone; (2) monoclonal antibodies (that are similar to the antibodies that the human immune system uses to fight off bacteria and viruses) are "custom-designed" and can therefore be made

[1] In the United States, RAPTIVA was considered a very expensive drug; its average cost was approximately $17,000-$25,000 for one year of treatment. RAPTIVA was at all times substantially more expensive than the existing, equally effective traditional psoriasis treatment modalities.

specifically to counteract or block any given substance in the body, or to target any specific cell type; and, (3) receptor constructs (fusion proteins), usually based on a naturally-occurring receptor linked to the immunoglobulin frame.

10. RAPTIVA (produced in a Chinese hamster ovary cell expression system) is a recombinant humanized monoclonal antibody that binds to human CD11a, one of the two components which form lymphocyte function-associated antigen 1 (LFA-1). LFA-1 is an important molecule in lymphocyte adhesion, activation, and migration of tissues. It is involved in the recruitment of inflammatory cells to the site of infection. The skin lesions that occur in psoriasis are caused by the actions of T-cells that are attracted to the site of inflammation. LFA-1 is found on all T-cells, and also on B-cells, macrophages and neutrophils.

11. RAPTIVA was designed to inhibit the function of the T-cell by interfering with the ability of the LFA-1 to bind to the endothelium adhesion molecule ICAM-1 and migrate from the blood into the skin where it would promote an inflammatory response and the growth of skin lesions.

12. RAPTIVA's prevention of adhesion of LFA-1 (i) diminishes T-cell adhesion to the lining of blood vessels; (ii) decreases the migration of T-cells to sites of inflammation; (iii) reduces the potential of T-cells to kill malignant cells; and, (iv) contributes to the inhibition of activation of T-lymphocytes which are needed to fight infection.

13. It is generally accepted in the medical community that suppression of T-cell function predisposes the body to serious life-threatening infections (encephalitis, meningitis, and progressive multifocal leukoencephalopathy (PML), a rare brain infection) neurological complications, and the development of lymphoma, malignancy and possibly death.

14. It is generally accepted in the medical community that prolonged inhibition of (LFA-1) would impair the body's defenses against infection resulting in increased risk of infection, malignancy, lymphoma and death.

15. It is generally accepted in the medical community that the role of LFA-1 and its relationship to the body's immune system was well known long before RAPTIVA was approved in October 2003 for use in the management of patients with psoriasis.

B. XOMA AND GENENTECH'S RACE FOR FDA APPROVAL OF RAPTIVA

16. RAPTIVA was researched, developed, clinically tested, manufactured, advertised, marketed, promoted and sold by XOMA and GENENTECH in California.

17. In April 1996, XOMA entered into a collaboration agreement with GENENTECH for the development of RAPTIVA. Under the terms of the agreement, XOMA was responsible for the scale-up and development of RAPTIVA, and bringing it through Phase II clinical trials.[2] Upon meeting certain milestones, XOMA would have an option to participate in the development through U.S. approval, after which they would earn the right to co-promote and share in the profits in the United States and receive royalties on sales elsewhere. Pursuant to the agreement, GENENTECH purchased 1.5 million shares of XOMA stock and funded XOMA's research, design, development and testing costs for RAPTIVA through 1998.

18. In September 1996, XOMA filed an Investigational New Drug application (IND) with the U.S. Food and Drug Administration (FDA) for clinical testing of RAPTIVA (hu1124) for clinical testing of Raptiva in patients with moderate to severe psoriasis.

19. In 1998, XOMA met the original collaboration agreement milestones by successful completion of a Phase II trial and GENENTECH made a $2 million milestone payment to XOMA.

20. RAPTIVA was important to the future of XOMA. In its twenty years, XOMA had never turned a profit and if approved, RAPTIVA would be XOMA'S first attempt at commercial product which in turn would generate much needed revenue for the company. For that reason,

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[2] Clinical trials involving new drugs are commonly classified into four phases. Each phase of the drug approval process is treated as a separate clinical trial. **Phase I Clinical Trial** means a study designed to assess the metabolism and pharmacologic actions of a drug in humans, and the side effects associated with increasing dosage. **Phase II Clinical Trial** means studies in humans of the safety, dose ranging and efficacy of a pharmaceutical which have generated sufficient data to decide whether to commence Phase III Clinical Trials. **Phase III Clinical Trial** means a controlled study in humans of the efficacy and safety of a pharmaceutical product which is prospectively designed to demonstrate statistically whether the product is effective for use in a particular indication in a manner sufficient to obtain regulatory approval to market the product. **Phase IV Clinical Trial** mean such post approval studies that involve ongoing safety surveillance and ongoing technical support of a drug after it receives permission to be sold. Phase IV studies may be required by regulatory authorities or may be undertaken for other reasons (for example, the drug may not have been tested for interactions with other drugs, or on certain population groups such as pregnant women, who are unlikely to subject themselves to trials). The safety surveillance is designed to detect any long-term adverse effects over a much larger patient population and longer time period than was possible during the Phase I-III clinical trials. Harmful effects discovered by Phase IV trials may result in a drug being no longer sold, or restricted to certain uses: recent examples involve Rezulin and Vioxx.)

DEFENDANTS invested in the cross development of RAPTIVA for uses in other highly profitable disease markets, namely rheumatoid and psoriatic arthritis.

21. In December 1999, GENENTECH and XOMA announced initiation of Phase III Clinical Trials for RAPTIVA. DEFENDANTS intended to file a biologics license application (BLA) with the FDA by the end of 2001 in order to compete with rival drugs, Biogen's Amevive (alefacept) and Immunex Corp./Wyeth's Enbrel (etanercept) in the lucrative psoriasis market. RAPTIVA was expected to reach peak annual sales of $400 million if approved.

22. In April 2002, DEFENDANTS started a Phase II trial of RAPTIVA for treatment of patients with mild to moderate rheumatoid arthritis.

23. On April 5, 2002, DEFENDANTS reported that a RAPTIVA pharmacokinetic study failed. During Phase III testing, DEFENDANTS decided to relocate the RAPTIVA manufacturing facilities from XOMA to GENENTECH in order to allow for production of large-scale commercial quantities of RAPTIVA. The study suggested that the GENENTECH-sourced material achieved a higher serum concentration than the XOMA-material. The FDA asked GENENTECH to conduct a study of the "new" RAPTIVA in psoriasis patients due to the difference in the RAPTIVA serum concentration that was previously tested in patients. The comparability failure delayed RAPTIVA's approval filing with the FDA (December 2002) and significantly eroded RAPTIVA'S sales potential behind its competitors.

24. On December 27, 2002, GENENTECH submitted the RAPTIVA Biologic License Application to the FDA's Center for Biologics Evaluation and Research (STN BL 125075/0). At that time, XOMA reported the Biologic License Application was "based on efficacy and safety data from three Phase III studies[,]" which were conducted by XOMA.

25. In January 2003, the FDA approved the marketing of Biogen's Amevive for the treatment of psoriasis, one of DEFENDANTS' main competitors in the biologics psoriasis market. At the time, the competition to develop a treatment for psoriasis was intense. The first company to get its drug to market would gain a substantial first-mover advantage over companies entering the market later. The first-mover advantage typically resulted in bigger market share and broader

physician loyalty. The competition between Biogen and XOMA/GENENTECH was fierce. As TheStreet.com wrote:

> The best showdown will come between Biogen…and a tag team compromising Genentech…and XOMA. Both sides have a lot riding on the meeting because testing on their respective psoriasis drugs is largely completed and the drugs are about to be submitted to U.S. drug regulators. And while the companies won't admit it publicly, they have been slinging mud at each other. The stakes are high: American psoriasis sufferers could spend as much as $2 billion on the new drugs annually by 2005. XOMA is just plain desperate to push any drug to market. In 20 years, the company is still shooting blanks.…

26. On March 31, 2003, XOMA and GENENTECH entered into an amended collaboration agreement which set forth the terms and conditions relating to all aspects of its ongoing development and marketing of RAPTIVA. Specifically, DEFENDANTS agreed to joint development plans "designed to generate the preclinical, process development/manufacturing scale-up, clinical and regulatory information required for filing Drug Approval Applications in the Co-Promotion Territory."[3] Under the terms of the amended collaboration agreement, DEFENDANTS agreed to establish a Joint Steering Committee ("JSC") to oversee and manage the collaboration in the Co-Promotion Territory (the United States). The JSC was comprised of two representatives appointed and replaced at XOMA's discretion and two representatives appointed and replaced at GENENTECH's discretion. The JSC operated by consensus of the parties *to prevent Genentech from having sole decision-making authority pursuant to the Agreement*. The JSC was charged with (i) approving the development and commercialization strategies related to RAPTIVA; (ii) approving development and commercialization plans; (iii) approving annual budgets on collaboration projects and any subsequent increases; and (iv) settling disputes regarding any issue presented to the JSC that were unresolved by the Joint Core Team (JCT). The Joint Core Team reported to the JSC. Similar to the JSC, XOMA had an equal number of representatives (three) as GENENTECH for a total of six representatives and operated by consensus of the parties. JCT members were required to have preclinical development,

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[3] March 31, 2003, SEC Filing Form 8-K, Exhibit 2, Art 1.12

clinical development, process sciences, manufacturing, regulatory affairs, product development and/or marketing expertise. The JCT had responsibility with respect to the Co-Promotion Territory which included, but was not limited to, the following:

- Formulate strategy and plans for shared development and commercialization including but not limited to the annual marketing plans, broad product positioning, pricing, managed care contract strategies and Phase IV clinical support strategies;
- Prepare annual marketing and sales budgets;
- Provide progress updates to other team members with respect to development and commercialization activities and strategies; and
- Review and vote on Raptiva project proposals for future indications.

27. Under the terms of the 2003 amended collaboration agreement, GENENTECH was responsible for the transfer of all preclinical data, assays, and associated materials, protocols, procedures and any other information in GENENTECH's possession required for XOMA to initiate and complete clinical development of RAPTIVA, including any enabling studies and human clinical trials to the end of Phase II Clinical Trials for psoriasis. XOMA was responsible for all costs incurred in making any process improvements or refinements after GENENTECH's data and materials transfer.

28. Further, the amended collaboration agreement clearly detailed that XOMA was responsible for all development costs of RAPTIVA through the successful completion of the Phase II Clinical Trials.[4] XOMA was also responsible for a portion of the development costs incurred in Europe prior to the first regulatory approval permitting sale outside of the United States, up to an undisclosed amount for clinical trial work necessary for European regulatory approval.

29. XOMA invested and participated in RAPTIVA marketing events. In its August 13, 2003 quarterly SEC filings, XOMA reported (two months prior to FDA approval of RAPTIVA) that marketing, general and administrative expenses for the three months ended June 30, 2003 increased to $4.7 million, or an increase of 24%, from the prior year. "The most significant

[4] In 2000-2002, Raptiva accounted for more than 20% of XOMA's total research and development costs.

component of this increase was pre-launch activities for RAPTIVA. Pre-launch marketing expenses for RAPTIVA are expected to continue at similar or higher levels until the product launch date." In November 2004, one year after RAPTIVA's launch into U.S. markets, XOMA reported, "We have spent, and we expect to continue to spend, substantial funds in connection with, (among other things), sales and marketing of RAPTIVA." Under the terms of the amended collaboration agreement, XOMA received 25% of U.S. operating profits from RAPTIVA in the United States, and GENENTECH agreed to loan XOMA $80 million to continue the co-development of RAPTIVA. In addition, XOMA granted GENENTECH a security interest in XOMA'S profit share on RAPTIVA as collateral against any unpaid past due amounts of the loans. XOMA was granted a co-exclusive license from GENENTECH for the purpose of using, selling, having sold and offering for sale RAPTIVA in the United States. The consolidated accounting of operations for the RAPTIVA collaboration in the United States was referred to as "GenXOMA". A five-year long range plan for GenXOMA was established on a yearly basis under the direction of the JSC and submitted to GENENTECH and XOMA. Operation of GenXOMA was deemed commenced on the date the parties began to share development costs for the RAPTIVA Phase III Clinical Trials which occurred on or about May 4, 1999.

30. In 2003, XOMA reported RAPTIVA as one of the only three products it had in development. XOMA went on to state "whether [XOMA] can achieve profitability will be highly dependent on sales and expense levels from RAPTIVA, which [XOMA] has been developing under a collaboration agreement with Genentech….XOMA will share in the ultimate profits and losses from those sales."

31. On May 15, 2003, XOMA recorded a net quarterly loss of $13 million due in part to increased research and development fees related to RAPTIVA. The success of XOMA was critically tied to the success of RAPTIVA. The sooner RAPTIVA received FDA approval, the sooner XOMA would show a profit to their institutional investors and individual shareholders.

32. In May 2003, DEFENDANTS halted a clinical study developing RAPTIVA for the treatment of rheumatoid arthritis. An evaluation of the trial outcomes determined that RAPTIVA did not result in any noticeable clinical benefit in the patients receiving the drug. The results

were disappointing for DEFENDANTS' strategic visions of competing with the new biologic rheumatoid arthritis drugs two of which, Amgen's Enbrel and Johnson & Johnson's Remicade, had total sales of approximately $2 billion in 2002. One year later, DEFENDANTS announced RAPTIVA failed to show a significant benefit in patients suffering from psoriatic arthritis.

33. In August 2003, XOMA and GENENTECH reported that the FDA's Dermatologic and Ophthalmic Drug Advisory Committee would review their Biologics License Application (BLA).

34. The RAPTIVA BLA consisted of information, data, testing, design formulation, and the clinical studies of RAPTIVA conducted by both XOMA and GENENTECH.

35. FDA approval of the RAPTIVA Biologics License Application was based in part on the clinical studies data involving *XOMA manufactured RAPTIVA* as summarized in the table below:[5]

[5] Table 1 Efalizumab Studies: Psoriasis Subjects Receiving at Least One Dose of Efalizumab was submitted by DEFENDANTS to the FDA in the RAPTIVA BLA. The FDA's Center for Drug Evaluation and Research refers to Table 1 in its RAPTIVA approval package.

STN 125075: Efalizumab for Moderate to Severe Psoriasis
Clinical Review

Table 1 Efalizumab Studies: Psoriasis Subjects Receiving at Least One Dose of Efalizumab

Study	Phase and Design	Dose (mg/kg) and Route	Treatment Duration (wk)	No. of Subjects Treated 1st Time With XOMA	No. of Subjects Treated 1st Time With GNE
HU9602	1, open-label	0.03–10.0 IV	1	31	NA
HUPS249	1, open-label	0.1–1.0 IV	7	39	NA
HUPS252	2, placebo-controlled	0.1, 0.3 IV	8	97	NA
HUPS254	1, open-label	0.5–2.0 SC	1–8	52	NA
HUPS256	1, open-label	0.3–1.0 IV	12	11	NA
		1.0–4.0 SC	12	57	NA
ACD2058g	3, placebo-controlled	1.0–2.0 SC	12–24	462	NA
ACD2059g	3, placebo-controlled	1.0–4.0 SC	12–24	442	137
ACD2062g	3, open-label extension study to ACD2058g	1.0–2.0 SC	12	28	6
ACD2142g	1, open-label	1.0–2.0 SC	12	NA	70
ACD2243g	3, open-label	2.0 SC, then 1.0–2.0 SC	12 ≥ 48	NA	339
ACD2390g	3, placebo-controlled	1.0 SC	12	NA	368
ACD2391g	3, open-label extension to ACD2390g	1.0 SC	24	NA	174
ACD2600g	3, placebo-controlled	1.0 SC	12	NA	449
Subjects with psoriasis receiving efalizumab by manufacturer				1219	1543
Subjects with psoriasis receiving efalizumab (Total)				2762	

In addition to phase 1 and 2 trials, four phase 3 double blinded, randomized, placebo controlled trials were conducted. Long-term exposure data were provided by studies ACD2058g and ACD2059g (24 weeks of treatment), by study ACD2243g (48 weeks of treatment), and by the open-label extension studies. The total safety database consisted of over 2500 patients exposed to efalizumab.

36. At time of the application, DEFENDANTS submitted thirteen RAPTIVA clinical trials to the FDA. Of the thirteen trials, more than half were XOMA-conducted with XOMA-manufactured RAPTIVA. Only XOMA conducted all three clinical trial phases, and XOMA carried out the single, critical Phase II trial (human studies designed to evaluate the safety, dose ranging and efficacy of a pharmaceutical) submitted in the biologics application. Moreover, XOMA-manufactured RAPTIVA accounted for approximately 73% of the "long-term" exposure data submitted to the FDA (904 subjects—studies ACD 2058g/ACD2059g). GENENTECH-manufactured RAPTIVA accounted for approximately 27% (339 subjects-- ACD2243) of the "long-term" data submitted.

37. XOMA clinical trial data was utilized by DEFENDANTS and the FDA to support the warnings, precautions and adverse reaction information in the RAPTIVA packaged inserts (warning labels) and patient package inserts.

38. XOMA clinical trial data was incorporated into the marketed RAPTIVA label and package inserts and was relied upon by Plaintiff and his physicians.

39. On September 9, 2003, the FDA Advisory Committee recommended approval of RAPTIVA. XOMA shares rose more than 12 percent on the news. Its' shares had doubled in the two preceding months in anticipation of RAPTIVA approval due to DEFENDANTS' well-orchestrated, pre-approval publicity campaign that focused on messaging RAPTIVA efficacy and safety record to Wall Street, dermatologic institutions (such as the American Academy of Dermatology), and academics and universities with renowned dermatology departments/clinics. GENENTECH shares hit a 52-week high.

40. On September 24, 2003, two weeks after the FDA Advisory Committee recommended approval, XOMA sold 9,000,000 common shares and received approximately $67.2 million in net proceeds.

41. On October 23, 2003, the FDA approved the BLA for RAPTIVA.[6] At the time of approval, a total of 2,762 patients had been treated with RAPTIVA. Of those 2,762 patients, 2,400 had been treated for three months, 904 for six months, and only 218 for one year or more. While the panel approved RAPTIVA, several members raised concerns about long-term and interrupted use of the product.

42. Despite these safety concerns, the danger of prolonged or interrupted immunosuppression was ignored by DEFENDANTS and RAPTIVA was launched on November 17, 2003.

C. XOMA AND GENENTECH CONCEALMENT OF RAPTIVA'S SERIOUS HEALTH RISKS

i) Rebound Effect Leads to False Promotion of Raptiva as Safe for Continuous Long-Term Usage

[6] FDA approval was conditional on DEFENDANTS' commitment to conduct several post marketing surveillance studies with detailed final study protocols and final study reports required by the FDA, as well as additional manufacturing and performance testing for three validation runs and reevaluation of the product release specification.

43. DEFENDANTS had originally planned for RAPTIVA to be a 12-week course of treatment (similar to the competitor Biogen's psoriasis biologic, Amevive[7]). In development, however, RAPTIVA was plagued with numerous reports of patients having severe "rebound effects" who ceased using the biologic. RAPTIVA worked to clear up the skin lesions of psoriasis, but once a patient stopped taking the drug, the disease came back, sometimes in a more aggressive form than a patient's original baseline or pre-RAPTIVA treatment status. The rebounds (both on and off drug) occurred at new sites on the body where patients had never experienced psoriasis before; they were not flare-ups of existing psoriasis. In several patients who discontinued RAPTIVA, their plaque psoriasis turned into debilitating erythrodermic, guttae or pustular types of the disease[8]; some even required hospitalization.

44. DEFENDANTS knew the clinical trial data suggested that patients who stopped taking RAPTIVA relapsed and therefore it was apparent to DEFENDANTS that there was a need to remain on the drug for long periods of time, if not continuously for the rest of their lives because psoriasis is a chronic incurable disease. DEFENDANTS also knew that long-term immunosuppression increases the likelihood of serious life-threatening, infections (encephalitis, meningitis, PML), neurological complications, lymphomas, malignancies, and possibly death.

45. Nevertheless, DEFENDANTS, with a paucity of data to support their claims, made a strategic business decision to promote and market RAPTIVA as safe for "continuous treatment."

46. On September 9, 2003, DEFENDANTS made multiple material misrepresentations and omissions to the Dermatologic and Ophthalmic Drugs Advisory Committee of the FDA, falsely and deceptively reporting that RAPTIVA was safe for continuous usage:

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[7] Amevive, like RAPTIVA, is an immunosuppressive agent requiring once weekly injections. Unlike Raptiva, Amevive requires (i) in-office injections under a physician's supervision; (ii) blood work before initiating treatment and blood work every 2 weeks during the 12-week treatment course to monitor for lymphopenia, malignancies, serious infections; (iii) the initial 12-week course is followed by at least 12 weeks off treatment; and, (iv) retreatment is limited to one additional 12-week cycle. Amevive remains on the market today—the longest psoriasis biologic on market.

[8] Erythrodermic psoriasis is a particularly inflammatory form of psoriasis that often affects most of the body surface. Guttate psoriasis is an uncommon type of psoriasis in which small, red, teardrop-shaped spots appear on the arms, legs, and middle of the body. Pustular psoriasis is an extremely rare and severe form of psoriasis which involves raised bumps on the skin that are filled with pus (pustules) and which may require hospitalization or the use of strong systemic medications.

> Extended therapy with RAPTIVA provides increased clinical efficacy with no increase in adverse events. Overall, there were few serious adverse events associated with RAPTIVA therapy, no evidence of organ toxicity, and no evidence of increased malignancies or infections....RAPTIVA provides a significant new, safe, and efficacious alternative for patients with severe plaque psoriasis.[9]
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> "When the program began we did not know whether RAPTIVA would be best used intermittently or continuously, and during the course of these trials, it became clear that RAPTIVA is really best used continuously....RAPTIVA was well tolerated and safe for continuous use." ***Michelle Rohrer, Genentech Director of Regulatory Affairs***[10]
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> "Regarding continuous treatment, in contrast to loss of efficacy when Raptiva is discontinued, the efficacy of RAPTIVA improves with continuous treatment past 12 weeks." ***Lee Kaiser, Genentech Director of Clinical Biostatistics***[11]
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> "....RAPTIVA is a very safe and well-tolerated drug.... RAPTIVA'S safety profile over the extended treatment period appears as favorable as its safety profile over the short period." ""...many immunosuppressant drugs have the potential to cause increased risk of malignancies and infections. RAPTIVA is an immunosuppressant agent...The rates of infections and serious adverse events appear to remain constant over time. So based on this data, RAPTIVA'S safety profile is maintained with extended treatment." ***Richard Chin, Genentech Director of Clinical Research for the Specialty Biotherapeutics***.[12]
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> "Overall, there is a favorable adverse event profile, particularly with respect to infection and malignancy." ***Charles Johnson, Genentech Senior Director Clinical Development Group for Specialty Biotherapeutics***[13]

47. At all times material, DEFENDANTS provided no information regarding duration of treatment (continuous, long-term, indefinite use) in their product labeling for RAPTIVA and/or in DEFENDANTS' marketing materials. As a direct and proximate result of the failures of

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[9] FDA Dermatologic and Ophthalmic Drugs Advisory Committee Meeting (DODAC), Briefing Document, Executive Summary Conclusions, September 9, 2003.

[10] FDA DODAC Meeting, Transcript, September 9, 2003.

[11] FDA DODAC, Meeting Transcript, September 9, 2003.

[12] FDA DODAC Meeting Transcript, September 9, 2003.

[13] FDA DODAC Meeting Transcript, September 9, 2003.

DEFENDANTS to adequately disclose the risk of long-term continuous immunosuppresion to prescribing physicians in the United States, including Plaintiff's physicians and Plaintiff, physicians prescribed and over-prescribed RAPTIVA to patients, and both prescribing physicians and the consumer public, including Plaintiff, were grossly under-informed regarding the risks of serious health effects.

ii) No Required Diagnostic Monitoring to Conceal Serious Health Risks

48. Further, DEFENDANTS, despite their knowledge of the serious health risks associated with the continuous immunosuppressive therapy with RAPTIVA, failed to implement a patient monitoring program in order to provide early detection of serious life-threatening infections (encephalitis, meningitis, PML), neurological complications, lymphomas, and malignancies—all associated with immunosuppressant therapies. DEFENDANTS made a strategic business decision not to require any baseline blood work or physical exams prior to commencing RAPTIVA, nor institute a required weekly, monthly or quarterly health assessment during long-term continuous usage of RAPTIVA[14]. RAPTIVA patients were receiving a novel immunosuppressant agent with no required ongoing physician visits, physical exams, x-rays or regular blood or laboratory diagnostic assessments to monitor for serious health risks during RAPTIVA usage or prior to prescription renewal.

49. At all times material, DEFENDANTS falsely and deceptively explained away the need for monitoring requirements by indicating it "might not be good for patients", as Susan Desmond-Hellmann, Chief Medical Officer and Executive Vice President of Product Development and Product Operation at GENENTECH stated on September 9, 2003: ". . . while the physician may feel better, the real crux of the matter is, is it good for the patient to monitor their platelets monthly, every three monthly....when we looked at the data there's not really evidence that that's [monitoring] good for patients and so we'll have to balance what makes you [physicians] feel good and what's good for patients."[15],[16]

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[14] Genentech. RAPTIVA (efalizumab) package insert, 2003. "Patients should be informed that physicians *may* monitor their platelet count". (emphasis added)

[15] Genentech, Inc. Conference Call FDA's DODAC review of product RAPTIVA- Final. 2003.

[16] The average costs for laboratory diagnostic monitoring in the Untied States based on 2009 Medicare rates are calculated as follows: Complete physical, $123.00; CD4 T-lymphocyte, $90.00,; for a CBC w/platelet panel, $9.45; Chest x-ray, $45.00

50. DEFENDANTS' explanation was a pretextual. The real reason for not requiring medical monitoring was twofold: (i) to undermine the reporting by physicians and patients of the adverse health risks associated with RAPTIVA; and, (ii) for strategic marketing purposes, DEFENDANTS wanted to distinguish RAPTIVA as the easier and more convenient alternative to their main competitor, Amevive, which required administration in a physician's office and required monitoring every two weeks. "From a commercial standpoint, we would prefer not to see monitoring on a monthly basis..."[17] Diane L. Parks, GENENTECH's Vice President of Cardiovascular & Specialty Therapeutics, Marketing & Sales.

51. At all times material, DEFENDANTS knew and failed to inform Plaintiff, physicians and the general public that required monitoring would provide early detection and most likely prevent the very health risks which ultimately led RAPTIVA to be taken off the market: serious life-threatening infections (encephalitis, meningitis and PML), neurological complications, lymphomas, malignancies, and death. DEFENDANTS fought for years to keep safety concerns from destroying RAPTIVA's commercial prospects, thus enabling them to sell RAPTIVA as a premium psoriasis drug when it was not.[18]

iii) Direct Shipments to Patients Bypasses Physician Detection of Serious Health Risks

52. In order to maximize their profits from the sale of RAPTIVA and recoup their significant developmental costs, DEFENDANTS marketed RAPTIVA as "safe, effective, convenient, long-term, continuous control."

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[17] Genentech, Inc. Conference Call FDA's DODAC review of product RAPTIVA- Final. 2003.

[18] Although, RAPTIVA was one of the most costly psoriasis medications on the market, its effectiveness was no better than traditional psoriasis modalities of phototherapy and oral system agents. The 'Gold Standard' for the assessment of extensive psoriasis is the Psoriasis Area and Severity Index (PASI). Clinical trial outcomes are often reported in terms of average percentage change in PASI score from baseline to end point. PASI measures the average redness, thickness and scaliness of the lesions (each graded on a 0-4 scale), weighted by the area of involvement. PASI 75, a 75% improvement in PASI, is well established as a clinically meaningful endpoint for clinical trials in psoriasis. Raptiva PASI response rate at 12 weeks of treatment was 27% (PASI-75 response) and 59% (PASI-50 Response), Study 2390. The average PASI-75 at week 12 ranged from 17% to 37% among the four studies DEFENDANTS presented to the FDA DODAC in September 2003. (Study Nos. 2059, 2390, 2058, 2600). Members of the DODAC were concerned about RAPTIVA'S low efficacy rate: "We must emphasize only 1 out of 5 patients got a PASI 75, which is the gold standard. Only 13 percent without placebo got 90 percent or better. 13 percent." ***Dr. Robert Katz, M.D., Committee Member, Meeting of the DODAC, September 9, 2003.***

53. To support their marketing campaign of "convenient, continuous" use, DEFENDANTS developed a delivery system utilizing a network of specialty pharmacies[19] in which RAPTIVA (the biologic must be refrigerated) was delivered overnight directly to patient's homes—thereby bypassing the need for physicians' visits altogether which furthered the concealment of RAPTIVA's health risks.

54. At all times material, Plaintiff was able to receive his initial RAPTIVA prescription from his dermatologist or primary care physician and, without ever having the benefit of injection training from his physician's office, call a toll-free number to DEFENDANTS' specialty pharmacy, which, in turn, sent RAPTIVA directly to Plaintiff's home. Plaintiff's prescription renewal conveniently consisted of picking up the telephone and dialing a toll-free number to request more RAPTIVA—no physician visit, no physical exam, no diagnostic monitoring (x-rays, blood work, ct-scans) was required. Once an initial prescription was written, a patient never had to be seen again by a physician until, as in the instant case, a serious health problem arose.

iv) False Statements Touting Safety of Long-Term Usage While Ignoring Adverse Event Reports

55. From post-market approval in October 2003 until the time RAPTIVA was withdrawn from the market in 2009, DEFENDANTS repeatedly made false and deceptive statements regarding the safety of RAPTIVA and, by issuing a relentless series of press releases and publications touting RAPTIVA's "safety and efficacy" profile while concealing the truth about its serious life-threatening health risks and the adverse event reports associated with RAPTIVA usage.

56. On October 27, 2003, DEFENDANTS issued a joint press release to announce that the FDA had approved RAPTIVA. "RAPTIVA represents XOMA's first product approval and is the culmination of a highly successful collaboration with Genentech…The companies have worked

[19] Specialty pharmaceutical programs most commonly include injection therapies, high-cost therapies, and require specialized delivery and administration on an ongoing basis.

together on a robust clinical program that has demonstrated the safety and efficacy of RAPTIVA." said John L. Castello, XOMA's chairman, president and chief executive officer.

57. The next day, XOMA President Castello stated in an interview, "We think it's a tremendously competitive product, both with what's in the market now and what's coming....*It's got a very good safety profile -- we've seen no increase in cancer or organ damage.* It's convenient....Its efficacy looks very good." [20]

58. On November 19, 2003, DEFENDANTS issued a joint press release announcing the results of a study to be published in the *New England Journal of Medicine* in which patients who received extended treatment to 24 weeks continued to benefit from the drug. Hal Barron, GENENTECH's Vice President of Medical Affairs said, "These results clearly illustrate the benefit of continuous therapy with RAPTIVA and support the efficacy seen in over 3,000 patients treated with RAPTIVA in clinical trials to date."

59. On February 22, 2005, GENENTECH presented a three-year study of RAPTIVA at the American Academy of Dermatology which showed "long-term and sustained clearing in psoriasis patients with minimal side-effects." A same-day press release reported that adverse events in this study were similar to what had been observed in previous 12-week clinical trials of RAPTIVA: headache, non-specific infection (e .g. common colds), chills, pain, nausea, asthenia (weakness), and fever, all of which diminished after the first 1-2 doses. Further, the press release reported that *there was no evidence of cumulative toxicity or increased malignancy or infection.* A GENENTECH-paid clinical investigator, Craig Leonardi, M.D., stated in the press release "RAPTIVA is the first biologic therapy to show sustained benefit for psoriasis patients treated continuously over a three-year period. Given that psoriasis is a chronic disease, as dermatologists we must weigh the efficacy and safety of different treatment options over the long term. It is encouraging to see a consistent safety profile for RAPTIVA in this three-year open-label study."

60. On March 5, 2008, in another press release, GENENTECH continued to falsely and deceptively assert through its paid investigator, Dr. Craig Leonardi, that RAPTIVA was safe for

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[20] Oakland Tribune: *Psoriasis Drug Ok,* October 28, 2003. (emphasis added)

long-term continuous use: "Final results of the first three-year prospective efficacy and safety study of RAPTIVA was recently published....RAPTIVA demonstrated sustained safety long-term efficacy and a favorable safety profile in this three-year trial. These features make it appropriate for continuous, long-term treatment of plaque psoriasis."

61. These statements were repeated in countless continuing medical education symposiums and complimented by numerous papers in peer-reviewed medical literature by DEFENDANTS' employees and paid consultants, all of which attempted to downplay concerns about the adverse long-term continuous use of RAPTIVA.

62. While touting RAPTIVA's safety of long-term continuous use, DEFENDANTS falsely and deceptively failed to inform physicians and the public that by March 5, 2008, DEFENDANTS had knowledge and receipt of approximately 60 adverse event reports of patient deaths while on RAPTIVA, and over one hundred adverse event report of serious life-threatening infections leading to hospitalizations.[21]

63. DEFENDANTS failed to timely and appropriately amend, change, supplement, alter, or otherwise update the product labeling, package insert, or to otherwise advise physicians, patients, pharmacists, or other health care providers of the increasing number of adverse events reported, specifically the number of serious infections leading to hospitalizations, the number of malignancies and lymphomas and the number of deaths reported, and otherwise omitted such data and information regarding the aforementioned dangers associated with the use of RAPTIVA in the information shared with the medical community and the consumer public.

64. Despite the increasing number of adverse events reported after FDA approval of RAPTIVA, DEFENDANTS refused to modify or amend the RAPTIVA label to include a black box warning, the highest level of warning, for increased risk of serious life-threatening infections (encephalitis, meningitis, PML), neurological complications, lymphomas, malignancies and death, and/or require patient monitoring to ensure safe usage of RAPTIVA and early detection of health risks.

[21] FDA Adverse Event Reporting System (AERS) --RAPTIVA Freedom of Information Request.

65. In October 2008, after five years on the market, the FDA finally issued a boxed warning for RAPTIVA highlighting the risk of life-threatening neurological complications, bacterial and viral infections including bacterial sepsis, viral meningitis, invasive fungal disease and other opportunistic infections, as well as increased risk of cancer. The FDA also included a boxed warning specifically for PML. The FDA had received reports of serious infection leading to hospitalization, and death in patients using RAPTIVA.

66. In February 2009, the FDA issued a Public Health Advisory concerning three deaths in patients treated with RAPTIVA. Two involved people with confirmed cases of progressive multifocal leukoencephalopathy. The third death was a person believed to have contracted the brain infection, according to the advisory.

67. On February 20, 2009, the European Medicines Agency recommended to the European Commission the suspension of the marketing for RAPTIVA. After reviewing a comprehensive benefit-risk re-assessment, the EMEA's Committee for Medicinal Products for Human Use concluded that the benefits of RAPTIVA no longer outweighed its risks. In the European Union, physicians were advised not to issue *any* new prescriptions for RAPTIVA.

68. On February 20, 2009, Canada suspended the sales of RAPTIVA due to safety concerns. On April 8, 2009, after more reports of serious injury DEFENDANTS announced a phased withdrawal of RAPTIVA from United States markets due to safety concerns. On June 8, 2009, RAPTIVA was removed from U.S. markets. RAPTIVA is the first drug GENENTECH withdrew from the market in its 33-year history.[22]

69. At the time RAPTIVA was removed from the market there were nearly 100 *reported* adverse events of deaths, hundreds of reported adverse events of serious infection requiring hospitalization and numerous reports of debilitating rebound effects, also requiring hospitalization.

D. DEFENDANTS DEVELOPED A UNIFORM MARKETING STRATEGY TO CONCEAL RAPTIVA RISKS FROM PHYSICIANS AND PLAINTIFF

[22] On September 20, 2009, without the benefit of RAPTIVA's sales royalties, XOMA received a delisting warning from the NASDAQ exchange.

70. Even before DEFENDANTS received FDA approval to market RAPTIVA, they engaged in an intensive, pre-release marketing campaign to bolster physician and patient interest as well as product orders. DEFENDANTS' pre-release marketing campaign conveyed the uniform message that RAPTIVA was safe and effective for psoriasis treatment while omitting any significant negative clinical findings or lacked sufficient testing.

71. DEFENDANTS concealed RAPTIVA's safety risks from both physicians and the public in DEFENDANTS' marketing campaigns. DEFENDANTS knew that publicizing the necessity of continuous long-term or chronic usage of an immunosuppressant for psoriasis would cut into DEFENDANTS' projected profits by reducing the number of people for whom RAPTIVA could be prescribed and making the drug generally less attractive to physicians and patients.

72. In order to achieve a national rollout of DEFENDANTS' uniform marketing message, GENENTECH hired approximately 76 specialty RAPTIVA sales representatives. DEFENDANTS' sales force profiled and targeted high-value or top-prescribers in the area of psoriasis dermatology as well as prominent advocates and opinion leaders in psoriasis academia and research institutions. DEFENDANTS' sales force also focused on community physicians based upon their involvement in psoriasis.

73. To further promote RAPTIVA and increase the total market share and sales of the drug, DEFENDANTS hired public relations, marketing, and advertising firms, provided promotional materials to sales forces, sent direct mailers, email and quarterly RAPTIVA newsletters to physicians and their offices, sponsored studies and paid academics to publish papers in medical journals which "supported" the safety of RAPTIVA, provided media contacts with promotional materials, created and hosted a RAPTIVA website, advertised RAPTIVA on third party websites (including, but not limited to WebMD, Health.com, American Academy of Dermatology, and the National Psoriasis Foundation websites), provided financial assistance to RAPTIVA patients who spoke positively about their "RAPTIVA experience" to the FDA, physicians and to DEFENDANTS' own sales force.

74. Besides utilizing their RAPTIVA sales force, DEFENDANTS engaged in a widespread plan to fraudulently and falsely market RAPTIVA as a safe and effective psoriasis drug through

the media, academia, and through direct-to-physician and direct-to-consumer marketing. Direct-to-consumer and direct-to-patient channels included the internet, call centers, and direct email.

75. DEFENDANTS also sponsored a "Cleary You" campaign, a free program to RAPTIVA patients that encouraged adherence to treatment through education, psoriasis management tools, a toll-free nurse helpline, a members-only website, mailings, email-mailings and opportunities to network with other patients.

76. GENENTECH maintained, managed and operated a company website (www.gene.com) from their South San Francisco headquarters, which included a RAPTIVA medical page for physicians and patients, including Plaintiff, to obtain information on RAPTIVA. GENENTECH's website also contained information and enrollment forms about the company's Access to Care Foundation and Single Point of Contact programs.

77. DEFENDANTS employed personnel to navigate and assist patients, including Plaintiff, and their physicians with insurance coverage and/or financial assistance for RAPTIVA. DEFENDANTS' sales force educated physicians and physicians' staff regarding RAPTIVA, the specialty pharmacies available to deliver RAPTIVA, and DEFENDANTS' patient assistance and benefit reimbursement plans, Genentech's Access to Care Foundation ("GATCF") and Single Point of Contact (SPOC).

78. DEFENDANTS' SPOC and GATCF patient assistance programs allowed physicians and eligible patients, including Plaintiff, to limit the overall expense of RAPTIVA. After providing DEFENDANTS with the patient's requisite personal medical and financial information, the patient and their physicians were given a toll-free number to call, in California, and speak with GENENTECH representatives for pertinent enrollment information and eligibility decisions. The GENENTECH-sponsored patient assistance programs were administered and managed from GENENTECH's California headquarters.

79. In addition, DEFENDANTS direct to physician marketing channels included conducting online physician continuing medical education programs or "webinars", direct emails touting the safety and efficacy of RAPTIVA to physicians and physicians' staff, sending quarterly

RAPTIVA newsletters to physicians and their staff (DermMD, DermPA, DermNurse), conducting regional physician seminars, hiring key opinion leaders to support GENENTECH's false and misleading marketing campaign, and presenting papers and posters at prominent conventions by medical groups specializing in dermatology, which conventions are well-attended by psoriasis prescribers and medical groups such as the American Academy of Dermatology.

80. Despite their knowledge of the potentially life-threatening diseases associated with increased use of RAPTIVA and their knowledge of significant adverse events reported while on RAPTIVA, DEFENDANTS engaged in a marketing and advertising program that, as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that RAPTIVA was safe and effective for human use, had fewer side effects and adverse reactions than other methods of treating psoriasis, and would not result in any side effect that was potentially fatal.

81. DEFENDANTS falsely and deceptively withheld relevant information from prescribing physicians and RAPTIVA users in order to minimize user and physician concern regarding the safety and efficacy of the drug.

82. DEFENDANTS downplayed and understated the health hazards and risks associated with the use of RAPTIVA, and, through promotional literature as well as sales visits to prescribing physicians, deceived prescribing physicians and potential users of RAPTIVA by relaying positive information, while concealing the nature and extent of known adverse and serious health effects.

83. The information produced and disseminated by and on behalf of DEFENDANTS falsely and deceptively misrepresented a number of facts regarding RAPTIVA, including, but not limited to, the lack of adequate testing of RAPTIVA, and the nature, severity, and frequency of serious side effects leading to hospitalizations and adverse event reports caused by RAPTIVA.

84. At all times material, DEFENDANTS knew that RAPTIVA had a strong potential to increase the risk of serious life-threatening infection and reactivate latent, chronic infections.

DEFENDANTS also possessed knowledge that RAPTIVA had the potential to increase the risk of lymphomas and other malignancies.

85. At all times material, DEFENDANTS failed to warn patients of RAPTIVA's risk of serious life-threatening infections including PML, encephalitis and meningitis, as well as lymphomas, malignancies and death. Despite knowing that RAPTIVA posed the risk of serious injuries for anyone who took the drug, DEFENDANTS pushed RAPTIVA to market on unfounded claims of efficacy and safety while downplaying altogether and denying the drug's life-threatening risks.

86. DEFENDANTS intentionally diverted attention from RAPTIVA's risks and dangers by providing minimal information regarding such risks and dangers without having performed any significant studies on long-term usage of RAPTIVA. Had Plaintiff had known the risks and dangers associated with RAPTIVA, Plaintiff would not have taken RAPTIVA, and consequently, would not have been subject to its dangerous side effects.

87. The physicians who prescribed RAPTIVA to Plaintiff relied on the representations made by DEFENDANTS, prior to the date of prescribing RAPTIVA for use. The physicians relied on the representations regarding the safety of RAPTIVA, and would not have recommended for use or prescribed RAPTIVA if they had known the true facts regarding the safety of RAPTIVA.

88. Prior to the date upon which RAPTIVA was prescribed to Plaintiff, DEFENDANTS knew, or should have known, that RAPTIVA was extremely dangerous and unsafe for use by the general public. The dangers of this product included, by way of example, the likelihood of developing serious life-threatening infections such as PML, encephalitis and meningitis, as well as lymphomas, malignancies and death. DEFENDANTS failed to take appropriate action to cure the nature of these defects or to appropriately warn users of the product or their physicians of such dangerous characteristics.

89. DEFENDANTS thereby acted with malice toward Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing DEFENDANTS for their conduct, in an amount sufficiently large to be an example to others and to deter these DEFENDANTS and

others from engaging in similar conduct in the future. The aforesaid wrongful conduct was done with the advance knowledge, authorization, and ratification of one or more officer, director, or managing agents of DEFENDANTS.

SPECIFIC FACTUAL ALLEGATIONS TO CARY MASSA

90. From on or about February 2006 to January 2008, Plaintiff Massa was prescribed RAPTIVA by Dr. Soloman Brickman, Houston Laser Skin Center, Houston, Texas, and injected himself with RAPTIVA, which was tested, manufactured and distributed by DEFENDANTS for the treatment of psoriasis.

91. Because of the misleading information that DEFENDANTS, and each of them, provided to physicians and the FDA about the true risks associated with the use of RAPTIVA and because of the failure of the DEFENDANTS to adequately inform physicians generally including Plaintiff's physicians, about the true risks associated with the use of RAPTIVA, at all times relevant to this lawsuit, while Plaintiff Massa was taking RAPTIVA, his physicians never informed him of the risk of developing serious and permanent injuries, including Hodgkin's lymphoma, associated with RAPTIVA.

92. Plaintiff Massa, 51 years old, began experiencing a persistent cough in approximately October 2007. He also experienced nausea and vomiting, general malaise, reflux and weight loss. He treated with his primary care physician, Dr. Viswanath Kalapatapu, Katy, Texas, for these symptoms. In approximately February 2009, Plaintiff Massa presented to the emergency department at the Crispus St. Catherine Hospital, Katy, Texas with a painful left neck lymphadenopathy. After several diagnostic tests, including an upper endoscopy, colonoscopy, needle aspiration and excisional biopsy, Plaintiff Massa was diagnosed with Classic Hodgkin's lymphoma in approximately March 2009. CT scans of his neck, chest and abdomen revealed extensive, multiple lymphadenopathies both above and below the diaphragm.

93. In approximately April 2009, Plaintiff Massa received chemotherapy at MD Anderson Cancer Clinic, Houston, Texas under the care of Dr. Anas Younes.

94. Use of RAPTIVA caused Plaintiff Masssa to suffer serious, permanent and disabling injuries including, but not limited to, injuries associated with lymphoma. Because of injuries Plaintiff Massa suffered from the use of RAPTIVA, Plaintiff Massa has experienced and will continue to experience medical and related expenses, pain and suffering, psychological injury and other injuries and damages.

CLAIMS AGAINST DEFENDANT GENENTECH
FIRST CAUSE OF ACTION
[Strict Liability in Tort: Failure to Warn]

95. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

96. At all times mentioned in this Complaint, RAPTIVA was defective and unsafe in manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings and prepare for use and sell, and was so at the time it was distributed by Defendant GENENTECH and injected by Plaintiff. RAPTIVA was defective in that it was not properly prepared and was not accompanied by proper warnings, regarding all possible adverse side effects associated with the use of RAPTIVA, and given the severity of the adverse effects, the warnings given did not accurately reflect the symptoms and severity of the adverse effects. The product was also defective in that the product manufactured and distributed differed from the manufacturer's intended results. These defects caused serious injury to the user when used in its intended and foreseeable manner, and in the manner recommended by Defendant GENENTECH.

97. Defendant GENENTECH knew that RAPTIVA was to be used by the user without inspection for defects therein.

98. RAPTIVA was unaccompanied by warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of RAPTIVA involved substantial dangers not readily recognizable by the ordinary user of the product. Defendant GENENTECH failed to warn of the known or knowable likelihood of injury including but not limited to the likelihood the user would develop

serious infections such as PML, encephalitis and meningitis, as well as lymphomas, malignancies and death.

99. RAPTIVA was designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors by Defendant GENENTECH and was further defective due to inadequate post-marketing warning or instruction because, after Defendant GENENTECH knew or should have known of the risks of injury from RAPTIVA, they failed to promptly respond to and warn about the likelihood of serious injury as described herein.

100. Plaintiff did not know, nor had reason to know, at the time of the use of RAPTIVA, or at any time prior thereto, of the existence of the foregoing described defects. These defects caused the herein described injuries to Plaintiff.

101. Defendant GENENTECH knew that RAPTIVA was to be used by the user without inspection for defects therein and that RAPTIVA was unaccompanied by warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

102. Plaintiff neither knew, nor had reason to know, at the time of the use of RAPTIVA, or at any time prior thereto, of the existence of the foregoing described defect.

WHEREFORE, Plaintiff Massa prays for judgment against Defendant GENENTECH as hereinafter set forth.

SECOND CAUSE OF ACTION--GENENTECH
[Strict Products Liability Pursuant to Restatement Second of Torts §402A]

103. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

104. The RAPTIVA manufactured and supplied by Defendant GENENTECH was placed into the stream of commerce by Defendant GENENTECH in a defective and unreasonably dangerous condition in that the foreseeable risks exceeded the benefits associated with the design or formulation.

105. Alternatively, the RAPTIVA manufactured and supplied by Defendant GENENTECH was defective in design or formulation in that when it was placed in the stream of commerce, it was unreasonably dangerous and it was more dangerous than an ordinary consumer would expect and more dangerous than other forms of alternative traditional plaque psoriasis treatment.

106. The RAPTIVA manufactured and supplied by Defendant GENENTECH was defective due to inadequate warning or instruction because the Defendant GENENTECH knew or should have known that the product created a serious risk of harm to consumers and Defendant GENENTECH failed to adequately warn of said risks.

107. The RAPTIVA manufactured and supplied by Defendant GENENTECH was defective due to inadequate warning and inadequate testing.

108. The RAPTIVA manufactured and supplied by Defendant GENENTECH was defective due to inadequate post-marketing warnings and instructions, because Defendant GENENTECH knew or should have know of the risk of serious injury from RAPTIVA, however said DEFENDANT failed to provide adequate warnings to users or consumers of the product and continued to promote the product.

109. As a proximate and legal result of the defective and unreasonably dangerous condition of RAPTIVA tested, manufactured and supplied by Defendant GENENTECH, Plaintiff was caused to suffer the herein described injuries.

WHEREFORE, Plaintiff Massa prays for judgment against Defendant GENENTECH as hereinafter set forth.

THIRD CAUSE OF ACTION--GENENTECH
[Negligence]

110. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

111. Defendant GENENTECH had a duty to exercise reasonable care in the manufacture, sale and/or distribution of RAPTIVA into the stream of commerce, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects.

112. Defendant GENENTECH failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of RAPTIVA into interstate commerce in that Defendant GENENTECH knew or should have known that RAPTIVA created a high risk of unreasonable, dangerous side effects.

113. Defendant GENENTECH was negligent in the designing, manufacture, testing, advertising, warning, marketing and sale of RAPTIVA.

114. Despite the fact that Defendant GENENTECH knew or should have known that RAPTIVA caused unreasonable, dangerous side effects, GENENTECH continued to market the RAPTIVA to consumers including Plaintiff.

115. Defendant GENENTECH knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

116. Defendant GENENTECH willfully and deliberately failed to avoid those consequences, and in doing so, Defendant GENENTECH acted with a conscious disregard of the safety of Plaintiff.

117. Defendant GENENTECH's negligence was a proximate cause of Plaintiff's injuries, harm and economic loss which they suffered and will continue to suffer as previously described.

WHEREFORE, Plaintiff Massa prays for judgment against Defendant GENENTECH as hereinafter set forth.

FOURTH CAUSE OF ACTION--GENENTECH
[Breach of Implied Warranty]

118. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

119. At all times mentioned in this Complaint, Defendant GENENTECH manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold RAPTIVA, and prior to the time it was prescribed to Plaintiff, Defendant

GENENTECH impliedly warranted to Plaintiff, and to Plaintiff's agents, that RAPTIVA was of merchantable quality and safe for the use for which it was intended.

120. Plaintiff and his agents relied on the skill and judgment of the Defendant GENENTECH in using RAPTIVA.

121. The product was unsafe for its intended use, and it was not of merchantable quality, as warranted by Defendant GENENTECH, in that it had very dangerous propensities when put to its intended use and would cause severe injury to the user. RAPTIVA was unaccompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution.

122. As a proximate and legal result of the defective and unreasonably dangerous condition of RAPTIVA manufactured and supplied by Defendant GENENTECH, Plaintiff was caused to suffer the herein described injuries.

123. After Plaintiff was made aware that his injuries were a result of RAPTIVA, notice was duly given to Defendant GENENTECH of the breach of said warranty.

WHEREFORE, Plaintiff Massa prays for judgment against Defendant GENENTECH as hereinafter set forth.

FIFTH CAUSE OF ACTION--GENENTECH
[Breach of Express Warranty]

124. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

125. The aforementioned manufacturing, compounding, packaging, designing, distributing, testing, constructing, fabricating, analyzing, recommending, merchandizing, advertising, promoting, supplying and selling of RAPTIVA was expressly warranted to be safe for use by Plaintiff, and other members of the general public.

126. At the time of the making of the express warranties, Defendant GENENTECH had knowledge of the purpose for which RAPTIVA was to be used and warranted the same to be in all respects, fit, safe, and effective and proper for such purpose. RAPTIVA was unaccompanied

by warnings of its dangerous propensities that were either known or knowable at the time of distribution.

127. Plaintiff and his physicians reasonably relied upon the skill and judgment of Defendant GENENTECH, and upon said express warranty, in using RAPTIVA. The warranty and representations were untrue in that the product was unsafe and, therefore, unsuited for the use for which it was intended. RAPTIVA could and did thereby cause Plaintiff to sustain severe injuries as alleged in this Complaint

128. As soon as the true nature of the product and the fact that the warranty and representations were false were ascertained, Defendant GENENTECH was notified of the breach of said warranty.

WHEREFORE, Plaintiff Massa prays for judgment against Defendant GENENTECH as hereinafter set forth.

SIXTH CAUSE OF ACTION--GENENTECH
[Fraud by Concealment]

129. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

130. At all times mentioned in this Complaint, Defendant GENENTECH had the duty and obligation to disclose to Plaintiff and to his physicians, the true facts concerning RAPTIVA, that is, that RAPTIVA was dangerous and defective, and likely to cause serious health consequences to users, including injuries as described in this Complaint.

131. Defendant GENENTECH concealed important facts from Plaintiff Massa and from Plaintiff's physicians which facts include, but are not limited to, that Defendant GENENTECH had received numerous RAPTIVA adverse events reports resulting in death and numerous adverse event reports of serious infection and severe rebound effects during the same timeframe Plaintiff was prescribed and injecting RAPTIVA.

132. At all times mentioned in this Complaint, Defendant GENENTECH made affirmative representations to Plaintiff and his prescribing physicians prior to the day RAPTIVA was first

prescribed to Plaintiff that RAPTIVA was safe as set forth above while concealing the material facts set forth herein.

133. At all times mentioned in this Complaint, Defendant GENENTECH had the duty and obligation to disclose to Plaintiff and to his physicians the true facts concerning RAPTIVA, which facts include, but are not limited to, the fact that long term continuous use would cause injuries, including, but not limited to, debilitating rebound effects, serious life-threatening infections (encephalitis, meningitis and PML), lymphomas, malignancies and death.

134. At all times mentioned in this Complaint, Defendant GENENTECH intentionally, willfully, and maliciously concealed or suppressed the facts set forth above from Plaintiff's physicians, and therefore from Plaintiff, with the intent to defraud as alleged herein.

135. At all times mentioned in this Complaint, neither Plaintiff nor his physicians were aware of the concealed facts set forth herein. Had they been aware of those facts, they would not have acted as they did, that is, that RAPTIVA would not have prescribed in the treatment of Plaintiff's psoriasis and Plaintiff would not have injected it from April 2004 to November 2008.

136. Had Plaintiff been informed of the deaths, serious infections and debilitating rebound effects adverse reports associated with RAPTIVA usage, Plaintiff would have immediately discontinued RAPTIVA.

137. As a proximate result of the concealment or suppression of the facts set forth above, Plaintiff and his physicians' reasonably relied on Defendant GENENTECH's deception and, Plaintiff was prescribed and injected RAPTIVA and subsequently sustained injuries and damages as set forth in this Complaint. Defendant GENENTECH's concealment was a substantial factor in causing Plaintiff's injuries.

138. In doing the acts herein alleged, Defendant GENENTECH acted with oppression, fraud, and malice and Plaintiff is entitled to punitive damages in an amount reasonably related to Plaintiff's actual damages, and to Defendant GENENTECH's wealth, and sufficiently large to be an example to others, and to deter Defendant GENENTECH and others from engaging in similar conduct in the future.

SEVENTH CAUSE OF ACTION--GENENTECH
[Gross Negligence]

139. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

140. Defendant GENENTECH was grossly negligent in the designing, manufacture, testing, advertising, warning, marketing and sale of RAPTIVA.

141. Despite the fact that Defendant GENENTECH knew or should have known that RAPTIVA caused unreasonable, dangerous side effects, GENENTECH continued to market the RAPTIVA to consumers including Plaintiff.

142. Defendant GENENTECH knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

143. Defendant GENENTECH willfully and deliberately failed to avoid those consequences, and in doing so, Defendant GENENTECH acted with a conscious disregard of the safety of Plaintiff.

144. Defendant GENENTECH's conduct involved an extreme degree of risk, considering the probability and magnitude of the potential harm to patients who took RAPTIVA.

145. Defendant GENENTECH had actual subjective awareness of the risk associated with RAPTIVA and proceeded with conscious indifference to the rights, safety and welfare of patients who took RAPTIVA.

146. Defendant GENENTECH's negligence was a proximate cause of Plaintiff's injuries, harm and economic loss which they suffered and will continue to suffer as previously described.

WHEREFORE, Plaintiff Massa prays for judgment against Defendant GENENTECH as hereinafter set forth.

CLAIMS AGAINST DEFENDANT XOMA
EIGHTH CAUSE OF ACTION
[Strict Liability in Tort: Failure to Warn]

147. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

148. At all times mentioned in this Complaint, RAPTIVA was defective and unsafe in manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings and prepare for use and sell, and was so at the time it was distributed by Defendant XOMA and injected by Plaintiff. RAPTIVA was defective in that it was not properly prepared and was not accompanied by proper warnings, regarding all possible adverse side effects associated with the use of RAPTIVA, and given the severity of the adverse effects, the warnings given did not accurately reflect the symptoms and severity of the adverse effects. The product was also defective in that the product manufactured and distributed differed from the manufacturer's intended results. These defects caused serious injury to the user when used in its intended and foreseeable manner, and in the manner recommended by Defendant XOMA.

149. Defendant XOMA knew that RAPTIVA was to be used by the user without inspection for defects therein.

150. RAPTIVA was unaccompanied by warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of RAPTIVA involved substantial dangers not readily recognizable by the ordinary user of the product. Defendant XOMA failed to warn of the known or knowable likelihood of injury including but not limited to the likelihood the user would develop serious infections such as PML, encephalitis and meningitis, as well as lymphomas, malignancies and death.

151. RAPTIVA was designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors by Defendant XOMA and was further defective due to inadequate post-marketing warning or instruction because, after Defendant XOMA knew or should have known of the risks of injury from RAPTIVA, they failed to promptly respond to and warn about the likelihood of serious injury as described herein.

152. Plaintiff did not know, nor had reason to know, at the time of the use of RAPTIVA, or at any time prior thereto, of the existence of the foregoing described defects. These defects caused the herein described injuries to Plaintiff.

153. Defendant XOMA knew that RAPTIVA was to be used by the user without inspection for defects therein and that RAPTIVA was unaccompanied by warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

154. Plaintiff neither knew, nor had reason to know, at the time of the use of RAPTIVA, or at any time prior thereto, of the existence of the foregoing described defect.

WHEREFORE, Plaintiff Massa prays for judgment against Defendant XOMA as hereinafter set forth.

NINTH CAUSE OF ACTION--XOMA
[Strict Products Liability Pursuant to Restatement Second of Torts §402A]

155. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

156. The RAPTIVA tested, manufactured and supplied by Defendant XOMA was placed into the stream of commerce by Defendant XOMA in a defective and unreasonably dangerous condition in that the foreseeable risks exceeded the benefits associated with the design or formulation.

157. Alternatively, the RAPTIVA tested, manufactured and supplied by Defendant XOMA was defective in design or formulation in that when it was placed in the stream of commerce, it was unreasonably dangerous and it was more dangerous than an ordinary consumer would expect and more dangerous than other forms of alternative traditional plaque psoriasis treatment.

158. The RAPTIVA tested, manufactured and supplied by Defendant XOMA was defective due to inadequate warning or instruction because the Defendant XOMA knew or should have known that the product created a serious risk of harm to consumers and Defendant XOMA failed to adequately warn of said risks.

159. The RAPTIVA tested, manufactured and supplied by Defendant XOMA was defective due to inadequate warning and inadequate testing.

160. The RAPTIVA tested, manufactured and supplied by Defendant XOMA was defective due to inadequate post-marketing warnings and instructions, because Defendant XOMA knew or should have know of the risk of serious injury from RAPTIVA, however said Defendant failed to provide adequate warnings to users or consumers of the product and continued to promote the product.

161. As a proximate and legal result of the defective and unreasonably dangerous condition of RAPTIVA tested, manufactured and supplied by Defendant XOMA, Plaintiff was caused to suffer the herein described injuries.

WHEREFORE, Plaintiff Massa prays for judgment against Defendant XOMA as hereinafter set forth.

TENTH CAUSE OF ACTION--XOMA
[Negligence]

162. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

163. Defendant XOMA had a duty to exercise reasonable care in the manufacture, sale and/or distribution of RAPTIVA into the stream of commerce, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects.

164. Defendant XOMA failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of RAPTIVA into interstate commerce in that Defendant XOMA knew or should have known that RAPTIVA created a high risk of unreasonable, dangerous side effects.

165. Defendant XOMA was negligent in the designing, manufacture, testing, advertising, warning, marketing and sale of RAPTIVA.

166. Despite the fact that Defendant XOMA knew or should have known that RAPTIVA caused unreasonable, dangerous side effects, XOMA continued to market the RAPTIVA to consumers including Plaintiff.

167. Defendant XOMA knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

168. Defendant XOMA willfully and deliberately failed to avoid those consequences, and in doing so, Defendant XOMA acted with a conscious disregard of the safety of Plaintiff.

169. Defendant XOMA's negligence was a proximate cause of Plaintiff's injuries, harm and economic loss which they suffered and will continue to suffer as previously described.

WHEREFORE, Plaintiff Massa prays for judgment against Defendant XOMA as hereinafter set forth.

ELEVENTH CAUSE OF ACTION--XOMA
[Breach of Implied Warranty]

170. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

171. At all times mentioned in this Complaint, Defendant XOMA manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold RAPTIVA, and prior to the time it was prescribed to Plaintiff, Defendant XOMA impliedly warranted to Plaintiff, and to Plaintiff's agents, that RAPTIVA was of merchantable quality and safe for the use for which it was intended.

172. Plaintiff and his agents relied on the skill and judgment of the Defendant XOMA in using RAPTIVA.

173. The product was unsafe for its intended use, and it was not of merchantable quality, as warranted by Defendant XOMA, in that it had very dangerous propensities when put to its intended use and would cause severe injury to the user. RAPTIVA was unaccompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution.

174. As a proximate and legal result of the defective and unreasonably dangerous condition of RAPTIVA manufactured and supplied by Defendant XOMA, Plaintiff was caused to suffer the herein described injuries.

175. After Plaintiff was made aware that his injuries were a result of RAPTIVA, notice was duly given to Defendant XOMA of the breach of said warranty.

WHEREFORE, Plaintiff Massa prays for judgment against Defendant XOMA as hereinafter set forth.

TWELFTH CAUSE OF ACTION--XOMA
[Breach of Express Warranty]

176. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

177. The aforementioned manufacturing, compounding, packaging, designing, distributing, testing, constructing, fabricating, analyzing, recommending, merchandizing, advertising, promoting, supplying and selling of RAPTIVA was expressly warranted to be safe for use by Plaintiff, and other members of the general public.

178. At the time of the making of the express warranties, Defendant XOMA had knowledge of the purpose for which RAPTIVA was to be used and warranted the same to be in all respects, fit, safe, and effective and proper for such purpose. RAPTIVA was unaccompanied by warnings of its dangerous propensities that were either known or knowable at the time of distribution.

179. Plaintiff and his physicians reasonably relied upon the skill and judgment of Defendant XOMA, and upon said express warranty, in using RAPTIVA. The warranty and representations were untrue in that the product was unsafe and, therefore, unsuited for the use for which it was intended. RAPTIVA could and did thereby cause Plaintiff to sustain severe injuries as alleged in this Complaint

180. As soon as the true nature of the product and the fact that the warranty and representations were false were ascertained, Defendant XOMA was notified of the breach of said warranty.

WHEREFORE, Plaintiff Massa prays for judgment against Defendant XOMA as hereinafter set forth.

THIRTEENTH CAUSE OF ACTION--XOMA
[Fraud by Concealment]

181. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

182. At all times mentioned in this Complaint, Defendant XOMA had the duty and obligation to disclose to Plaintiff and to his physicians, the true facts concerning RAPTIVA, that is, that RAPTIVA was dangerous and defective, and likely to cause serious health consequences to users, including injuries as described in this Complaint.

183. Defendant XOMA concealed important facts from Plaintiff Massa and from Plaintiff's physicians which facts include, but are not limited to, that Defendant XOMA had received numerous RAPTIVA adverse events reports resulting in death and numerous adverse event reports of serious infection and severe rebound effects during the same timeframe Plaintiff was prescribed and injecting RAPTIVA.

184. At all times mentioned in this Complaint, Defendant XOMA made affirmative representations to Plaintiff and his prescribing physicians prior to the day RAPTIVA was first prescribed to Plaintiff that RAPTIVA was safe as set forth above while concealing the material facts set forth herein.

185. At all times mentioned in this Complaint, Defendant XOMA had the duty and obligation to disclose to Plaintiff and to his physicians the true facts concerning RAPTIVA, which facts include, but are not limited to, the fact that long term continuous use would cause injuries, including, but not limited to, debilitating rebound effects, serious life-threatening infections (encephalitis, meningitis and PML), lymphomas, malignancies and death.

186. At all times mentioned in this Complaint, Defendant XOMA intentionally, willfully, and maliciously concealed or suppressed the facts set forth above from Plaintiff's physicians, and therefore from Plaintiff, with the intent to defraud as alleged herein.

187. At all times mentioned in this Complaint, neither Plaintiff nor his physicians were aware of the concealed facts set forth herein. Had they been aware of those facts, they would not have acted as they did, that is, that RAPTIVA would not have prescribed in the treatment of Plaintiff's psoriasis and Plaintiff would not have injected it from approximately April 2004 to November 2008.

188. Had Plaintiff been informed of the deaths, serious infections and debilitating rebound effects adverse reports associated with RAPTIVA usage, Plaintiff would have immediately discontinued RAPTIVA.

189. As a proximate result of the concealment or suppression of the facts set forth above, Plaintiff and his physicians' reasonably relied on Defendant XOMA's deception and, Plaintiff was prescribed and injected RAPTIVA and subsequently sustained injuries and damages as set forth in this Complaint. Defendant XOMA's concealment was a substantial factor in causing Plaintiff's injuries.

190. In doing the acts herein alleged, Defendant XOMA acted with oppression, fraud, and malice and Plaintiff is entitled to punitive damages in an amount reasonably related to Plaintiff's actual damages, and to Defendant XOMA's wealth, and sufficiently large to be an example to others, and to deter Defendant XOMA and others from engaging in similar conduct in the future.

FOURTEENTH CAUSE OF ACTION--XOMA
[Gross Negligence]

191. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

192. Defendant XOMA was grossly negligent in the designing, manufacture, testing, advertising, warning, marketing and sale of RAPTIVA.

193. Despite the fact that Defendant XOMA knew or should have known that RAPTIVA caused unreasonable, dangerous side effects, XOMA continued to market the RAPTIVA to consumers including Plaintiff.

194. Defendant XOMA knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

195. Defendant XOMA willfully and deliberately failed to avoid those consequences, and in doing so, Defendant XOMA acted with a conscious disregard of the safety of Plaintiff.

196. Defendant XOMA's conduct involved an extreme degree of risk, considering the probability and magnitude of the potential harm to patients who took RAPTIVA.

197. Defendant XOMA had actual subjective awareness of the risk associated with RAPTIVA and proceeded with conscious indifference to the rights, safety and welfare of patients who took RAPTIVA.

198. Defendant XOMA's negligence was a proximate cause of Plaintiff's injuries, harm and economic loss which they suffered and will continue to suffer as previously described.

WHEREFORE, Plaintiff Massa prays for judgment against Defendant XOMA as hereinafter set forth.

JURY DEMAND

Plaintiff demands a jury in this case and has paid the requisite jury fee with the filing of this complaint.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against DEFENDANTS, and each of them, on each count as follows:

1. for general damages in a sum within the jurisdiction of this Court;
2. for past and future medical, hospital, and incidental expenses;
3. for loss of earnings and for loss of earning capacity;
4. for past and future pain and suffering;
5. for past and future emotional distress;
6. for past and future mental anguish;
7. for past and future physical impairment and/or disfigurement;
8. for lost of consortium;
9. for loss of household services;
10. for punitive or exemplary damages;
11. for costs of suit herein;
12. for reasonable attorney's fees;
13. for such other relief as the Court deems just and proper; and
14. for all applicable statutory remedies provided by law that assert liability for Defendants' wrongdoings and improper conduct

TOLLING OF THE LIMITATIONS PERIOD

15. DEFENDANTS, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with taking RAPTIVA.

16. As a result of DEFENDANTS' actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risk of injury identified in this Complaint, and that those risks were the result of DEFENDANTS' acts, omissions, and misrepresentations.

17. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between Plaintiff's injection of RAPTIVA and the harm Plaintiff suffered as a result.

18. Additionally, the accrual and running of any applicable statute of limitations has been tolled by reason of DEFENDANTS' fraudulent concealment.

19. Additionally, DEFENDANTS are equitably estopped from asserting any limitations defense by virtue of their fraudulent concealment and other misconduct as described.

20. Additionally, the limitations period ought to be tolled under principles of equitable tolling.

Dated: Jan 7, 2011.

W. Mark Lanier
SBN: 11934600
wml@lanierlawfirm.com
Ken Soh
SBN: 00794670
kss@lanierlawfirm.com
LANIER LAW FIRM, PC
6810 FM 1960 West
Houston, Texas 77069
Phone: (713) 659-5200
Fax: (713) 659-2204